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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/099,772 | 03/15/2002 | Gary L. Long | END-838 | 4856 |
| 27777 | 7590 | 07/08/2004 | EXAMINER | |
| PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003 | | | VRETTAKOS, PETER J | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3739 | |

DATE MAILED: 07/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/099,772 | LONG ET AL. |
| | Examiner | Art Unit |
| | Peter J Vrettakos | 3739 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 05 April 2004.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-23,25-27,29 and 30 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-23,25-27,29 and 30 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The instant action is non-final. Prior rejections have been obviated through the Applicant's persuasive arguments in the Response dated 7-2-04.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 1-8, 13-18, 20-22, 25-27, and 29 are rejected under 35 U.S.C. 102(b)
as being clearly anticipated by Komiya ('624).**

Independent claims 1, 14, 20, 29, respectively

Komiya discloses a method of treating tissue within a patient, said method comprising the steps of:

providing at least one instrument (catheter 5 which can envelop element 10; col.

3:32-35) having a distal end;

providing at least one channel (3) for accessing a treatment site;

extending at least a portion of the instrument from a distal end of the channel to access the treatment site (see figure 6); and

constraining motion (using instrument element 6 in figure 6) of the distal end of the instrument (catheter 5 which can envelop element 10; col. 3:32-35) along a

predetermined path (as determined by instrument element 6) at the treatment site.

Komiya discloses a method of treating tissue within a patient, said method comprising the steps of:

providing a first instrument (catheter 5 which can envelop element 10; col. 3:32-35) having a distal end;

providing a second instrument (6) having a distal end;

providing a first channel (3) for accessing a treatment site;

providing a second channel (4) for accessing a treatment site;

advancing the first instrument (catheter 5 which can envelop element 10; col. 3:32-35) from a distal end of the first channel to a treatment site within the patient (see figure 6);

advancing the second instrument from a distal end of the second channel (4) to the treatment site (*in the direction of the treatment site*, see figure 6);

and cooperating motion of the distal ends of the first (catheter 5 which can envelop element 10; col. 3:32-35) and second (6) instruments such that the distal ends follow a predetermined path (see figure 6).

Komiya discloses a method of treating tissue within a patient, said method comprising the steps of:

providing an endoscope having at least one instrument channel (3);

disposing the endoscope in a body lumen (8);
advancing a flexible instrument (catheter 5 which can envelop element 10; col. 3:32-35) from the distal end of the instrument channel to access a treatment site in the body lumen (see figure 6); and
constraining motion (using instrument element 6 in figure 6) of the distal end of the flexible instrument (catheter 5 which can envelop element 10; col. 3:32-35) along a desired path (90 degree angle with respect to the endoscope 1 shown in figure 6) as the instrument is advanced from the distal end of the instrument channel.

Komiya discloses a method of treating tissue within a patient, said method comprising:

attaching a mechanism (6) for guiding motion of a medical instrument (catheter 5 which can envelop element 10; col. 3:32-35) to the distal end of an endoscope (1);
inserting a first instrument (catheter 5 which can envelop element 10; col. 3:32-35) having a distal end through an instrument channel (3) of said endoscope; connecting the distal end of the medical instrument (catheter 5 which can envelop element 10; col. 3:32-35) to the mechanism (6);
inserting said endoscope with the mechanism and the medical instrument into the patient (8, figure 6).

Note: the reader is directed to the Applicant's figures 7-16 to appreciate the similarities to Komiya's invention in figures 3,6, and 12.

Dependent claims (Examiner's comments directed toward Komiya)

2. The method of Claim 1 wherein the step of constraining motion of the distal end of the instrument comprises restricting twisting of the instrument (catheter 5 which can envelop element 10; col. 3:32-35) about the longitudinal axis of the instrument (see figure 3, element 6 is attached at one point of element 5, thereby restricting twisting).
3. The method of Claim 1 wherein the step of constraining motion of the end of the instrument comprises bending the instrument (see figure 6, elements 5,6, and 10).
4. The method of Claim 3 wherein the step of bending the instrument comprises bending the instrument through an angle of at least about 90 degrees (element 5, figure 6).
5. The method of Claim 1 wherein the path is not parallel to a longitudinal axis of the channel (see figure 6 – the path is at a right angle or 90 degrees to the channel longitudinal axis).

6. The method of Claim 1 wherein the step of constraining motion of the end of the instrument comprises constraining motion of the end of the instrument along an arc (the arc is depicted in element 5 in which instrument 10 rests in figure 6).
7. The method of Claim 1 wherein the step of providing at least one channel comprises providing a channel having a proximal channel opening (inherent) outside the patient and a distal channel (shown in figure 3) opening within the patient.
8. The method of Claim 1 wherein the step of constraining motion of the end of the instrument comprises bending the instrument (catheter 5 which can envelop element 10; col. 3:32-35) to position the end of the instrument adjacent a lumen wall (8, see figure 6).
13. The method of Claim 1 wherein the first instrument comprises a hollow member, and wherein the method further comprises communicating a source of vacuum with the hollow member ("suction", col. 3:25-28).
15. The method of Claim 14 wherein the step of cooperating motion of the distal ends of the first (catheter 5 which can envelop element 10; col. 3:32-35) and second instruments (6) comprises engaging the distal ends of the first and second instruments, one with the other (figure 6).

16. The method of Claim 14 wherein the step of cooperating motion of the distal ends of the first and second instruments comprises bending *of the first instrument* (see figure 6).
17. The method of Claim 14 wherein the step of cooperating motion of the distal ends of the first and second instruments comprises preventing twisting *of the first instrument* (catheter 5 which can envelop element 10; col. 3:32-35) (see figure 6).
18. The method of Claim 14 wherein the step of cooperating motion of the distal ends of the first and second instruments comprises bending *the first instrument* through an angle of about 90 degrees (see figure 6).
21. The method of Claim 20 wherein the step of constraining motion of the end of the flexible instrument comprises bending the instrument (catheter 5 which can envelop element 10; col. 3:32-35) as the instrument is advanced from the instrument channel (see figures 2 and 3).
22. The method of Claim 20 wherein the step of bending the instrument (catheter 5 which can envelop element 10; col. 3:32-35) comprises bending the instrument through an angle of at least about 90 degrees (figure 6).
25. The method of Claim 20 wherein the step of constraining motion of the

end of the instrument comprises constraining motion of the end of the instrument along an arc (the arc is depicted in element 5 in figure 6).

26. The method of Claim 20 wherein the step of constraining motion of the end of the instrument (catheter 5 which can envelop element 10; col. 3:32-35) comprises positioning the distal end of the instrument adjacent a lumen wall (8, see figure 6).

27. The method of Claim 20 wherein the step of constraining the motion of the end of the instrument comprises positioning the distal end of the instrument to treat tissue located adjacent the perimeter of the distal end of endoscope (figure 6).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 9, 10, 11, 12, 19 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Komiya in view of Sekine et al. ('753).

9. Sekine et al. (Sekine) discloses an analogous method (with an analogous device but without an analogue to Komiya element 6) that further comprises the step of cutting a tissue sample (figure 11, col. 5:50-53; “mucous membrane”). Also note the embodiment in figure 7.

10. The method of Claim 9 further comprising the step of removing the tissue sample through the channel without removing the instrument from the channel (**Komiya** suction of viscous fluid, col. 3:25-28). Note: the Examiner contends that disclosure of “suction” is sufficient to make obvious “removing the tissue sample through the channel without removing the instrument.”

11. The method of Claim 1 further comprising the step of ablating tissue (Sekine discloses a high frequency power supply in col. 5:57, which makes obvious tissue ablation). Also, Sekine discloses other treatment methods involving lasers and HF probes (col. 1:33-36)

12. The method of Claim 1 further comprising the step of treating the tissue with argon plasma (see col. 1:33-36).

19. and 23. The method of Claim 18 or 22 wherein the step of cooperating motion of the distal ends of the first (Komiya catheter 5 which can envelop element 10; col. 3:32-35) and second (Komiya 6) instruments comprises bending the first (Sekine 13, which is

analogous to Komiya 5) through an angle of at least about 180 degrees (see Sekine figure 7).

Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to modify Komiya in view of Sekine by including additional applications (cutting, ablating) to which the disclosed device can perform. The motivation would be to increase the number of applications of the Komiya device.

Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Komiya in view of Sekine and further in view of Matsui et al. ('503).

30. Matsui et al. (Matsui) discloses an analogous method (with an analogous device – see figure 46) that further comprises the step of suturing tissue (method shown in figures 11,12 with a different embodiment).

Note: Matsui embodiment in figure 46 is nearly identical to the Sekine embodiment in figure 7. Both of these embodiments are the most relevant from these two patents to the rejections in this office action.

Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to modify Komiya in view of Sekine and further in view of Matsui by including

additional applications (suturing) to which the disclosed device can perform. The motivation would be to increase the number of applications of the Komiya device.

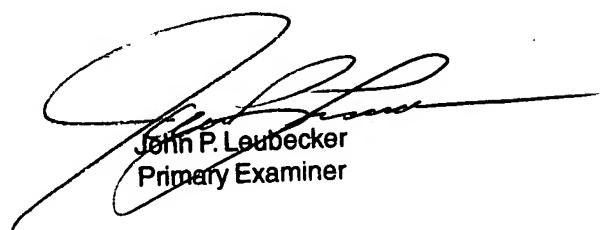
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J Vrettakos whose telephone number is 703 605 0215. The examiner can normally be reached on M-F 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C Dvorak can be reached on 703 308 0994. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pete Vrettakos
July 2, 2004

✓



John P. Leubecker
Primary Examiner